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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,138	10/06/2003	Hiroaki Oka	63979-034	3982

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EXAMINER	
WOOD, AMANDA P	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/678,138	OKA ET AL.
	Examiner	**Art Unit**
	Amanda P. Wood	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-12* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a)☒ All b)☐ Some * c)☐ None of:
  1.☐ Certified copies of the priority documents have been received.
  2.☐ Certified copies of the priority documents have been received in Application No. _____.
  3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION- Final Rejection

The amendment filed 17 January 2006 is acknowledged and has been entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1-2 and 6-9 stand rejected under 35 U.S.C. 102(e) as being anticipated by Petersen et al (US 6,682,649) for the reasons set forth in the previous Office action which are restated below.

Petersen et al teach a method of measuring activity signals of a biological sample (i.e., making electrophysiological measurements of the current flow through a cell membrane or other ion channel-containing structure) in the Abstract of the disclosure. Petersen et al further teach the use of a porous substrate (i.e., a perforated silicon substrate) whereby measurement chambers (also called, e.g., sites, wells, or test confinements) are created that have measurement electrodes on at least one side. In particular, Petersen et al specifically teach that the description of location and orientation of the substrate and electrodes merely refers to the orientation in the drawings, and that the invention could be used in an orientation corresponding to the figure being rotated at any angle (see, for example, col. 9, lines 10-50). Therefore, Petersen et al teaches a porous insulating substrate with integrated measuring electrodes wherein an ion-channel containing structure, such as a cell, is sealed onto the porous insulating substrate in contact with the measuring electrode (see, for example, col. 4, lines 5-60; col. 7, lines 1-45; and col. 8, lines 5-50). The method taught by Petersen et al also provides for the use of suction to pass the target liquid (carrier liquid) through the substrate, therefore establishing a giga seal between the substrate and biological sample (cell), allowing for measurement of the biological sample's activity signals through the measurement electrode (see, e.g., col. 3, lines 30-55). Petersen et al further teach that a plurality of electrodes can be contained on the substrate, creating a plurality of measurement chambers, or sites, allowing for several different measuring set-ups on a substrate. Therefore, different (or the same) target liquids (e.g., liquids containing different test samples, including pharmacological drugs) could be introduced (i.e., injected) to a plurality of different measurement chambers associated with a plurality of different measurement electrodes (see, e.g., col. 5, lines 10-65 and col. 17, lines 1-20).

Furthermore, Petersen et al teach a method wherein a conductor is formed on the porous insulating substrate via a mask layer, and is electrically connected to the measurement electrode (see, e.g., col. 8, lines 15-60). The method described by Petersen et al provides several different options for deposition of the conductor onto the substrate for formation of the electrode, one of which is sputtering (see, e.g., col. 7, lines 50-67).

Therefore, the cited reference is deemed to anticipate the instant claims above.

Applicants' arguments concerning the above USC 102 rejection have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that the cited reference fails to teach or even suggest that the measurement electrode is arranged on the front surface of the porous insulating substrate and that the biological sample is adsorbed to the measurement electrode. However, Petersen et al specifically teach that the substrate has measuring sites with integrated measuring electrodes, wherein the cell (i.e., biological sample) forms a seal around a measuring electrode (i.e., biological sample is adsorbed to the electrode), making it suitable for determining and monitoring a current flow through the cell membrane. In particular, Petersen et al teach that in Figure 3, the biological sample comes into contact with the AgCl layer of the electrode (i.e., adsorbs to the electrode), forming a seal with the electrode (see, for example, col. 8, lines 15-67). Furthermore, Petersen et al specifically point out that the substrate and measurement electrode can be oriented at any angle, not only in the orientation presented in the figures found in Petersen et al (see, for example, col. 9, lines 1-55)

Claim Rejections - 35 USC § 103

Claims 1-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al (US 6,682,649) in view of Owen et al (WO 99/663290) for the reasons set forth in the previous Office Action which are restated below.

The primary reference is relied upon for the reasons set forth above. Petersen et al reasonably teaches a method of measuring activity signals of a biological sample - as instantly claimed.

Petersen et al do not expressly teach the use of a particular porous insulating substrate. In claim 6, applicant refers to a porous insulating substrate composed of a resin film, having pore diameter between 1 μm and 1000 μm. Owen et al beneficially teach a method of using a porous substrate to monitor ion channel activity in a biological membrane (see, e.g., Abstract). Owen et al specifically point out that the porous substrate used may be any number of materials, including polytetrafluorotethylene (PTFE) and polyethylene terephthalate, both of which are considered to be resin-type materials (see, e.g., page 12, lines 5-10). Owen et al also teach that the diameter of the substrate pores should be between 1 μm and 7 μm (see, e.g., page 11, lines 15-20). Owen et al further teach that it would be beneficial to use such a porous insulating substrate so as to provide a means for screening a large number of samples, as well as to provide a means for a cell and substrate to create a high-resistance seal which would allow for monitoring of ion channel activity in a biological membrane (see, e.g., Abstract).

It would have been obvious for one of ordinary skill in the art at the time the claimed invention was made to modify the method of Petersen et al, by using the particular porous insulating substrate taught by Owen et al, so as to facilitate adsorption of biological cells to a measurement electrode provided with the porous insulating substrate. In particular, Petersen et al teach that the biological cell to be measured forms a high resistance seal around a measurement electrode found integrated onto the porous substrate. Furthermore, Owen et al teaches that it would be beneficial to use a porous insulating substrate to provide the means for high throughput screening of biological cells, such as to measure the activity signals of biological cells. In addition, the result-effective adjustment of particular conventional working conditions (e.g., using the measurement chamber and porous insulating substrate for more than one measurement of a target liquid or replacing the porous insulating substrate after each different target liquid is tested and/or evaluating the activity of such a biological sample based upon the conventional calculation of the standard deviation, mean value, and half-width of the obtained normal distribution of data collected) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Applicants' arguments concerning the above USC 103 rejection have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that the cited references fail to teach or suggest that the measurement electrode is arranged on the front surface of the porous insulating substrate and that the biological sample is adsorbed to the measurement electrode. However, Petersen et al specifically teach that the substrate has measuring sites with integrated measuring electrodes, wherein the cell (i.e., biological sample) forms a seal around a measuring electrode (i.e., biological sample is adsorbed to the electrode), making it suitable for determining and monitoring a current flow through the cell membrane. In particular, Petersen et al teach that in Figure 3, the biological sample comes into contact with the AgCl layer of the electrode (i.e., adsorbs to the electrode), forming a seal with the electrode (see, for example, col. 8, lines 15-67). Furthermore, Petersen et al specifically point out that the substrate and measurement electrode can be oriented at any angle, not only in the orientation presented in the figures found in Petersen et al (see, for example, col. 9, lines 1-55).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the particular porous insulating substrate used, and that the cells pass through the porous insulating substrate) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP §

706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 9:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

APW
Examiner
Art Unit 1655

APW

CHRISTOPHER R. TATE
PRIMARY EXAMINER